

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division**

ARIAD PHARMACEUTICALS, INC.,

Plaintiff,

v.

JOSEPH MATAL,

In his official capacity as Acting Under
Secretary of Commerce for Intellectual
Property and Director of the United States
Patent and Trademark Office

Defendant.

Civ. Action No. _____

COMPLAINT

Plaintiff, ARIAD Pharmaceuticals, Inc. (“ARIAD”), for its Complaint against the Honorable Joseph Matal, states as follows:

NATURE OF THE ACTION

1. This is an action by the assignee of United States Patent No. 8,114,874 (“the ’874 patent,” attached hereto as Exhibit 1) seeking review of the patent term adjustment granted by the Director of the United States Patent and Trademark Office (“PTO”) pursuant to 35 U.S.C. § 154(b). It is related to a prior action filed by ARIAD challenging the PTO’s previous calculation of patent term adjustment for the ’874 patent. *See Ariad Pharm., Inc. v. Lee*, No. 1:12-cv-886-TSE-TRJ (E.D. Va.).

2. On August 9, 2012, ARIAD filed a complaint against the PTO in this Court seeking review of the PTO’s patent term adjustment determination for the ’874 patent. On March 31, 2014, the Court remanded the matter to the PTO to recalculate the patent term

adjustment in light of the Federal Circuit's decision in *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014) ("*Novartis*"). The Court instructed the PTO to make a new patent term adjustment determination and set forth a time period during which ARIAD could request reconsideration if it disagreed with the determination. The Court stated that if ARIAD disagreed with the PTO's determination following reconsideration, it could seek review under 35 U.S.C. § 154(b)(4).

3. Following remand, the PTO failed to recalculate the patent term adjustment for the '874 patent for more than 21 months. On January 28, 2016, ARIAD filed with the PTO a petition requesting that the agency comply with the Court's instruction that it recalculate the patent term adjustment. On April 19, 2016, the PTO issued a decision recalculating the patent term adjustment for the '874 patent. The PTO's decision, however, continued to calculate an adjustment of zero days. On June 9, 2016, ARIAD filed a request for reconsideration. On March 9, 2017, the PTO denied ARIAD's request for reconsideration, determining that no patent term adjustment was warranted.

4. Pursuant to 35 U.S.C. § 154(b)(4)(A), ARIAD hereby seeks review of the PTO's failure to grant the proper amount of patent term adjustment.¹

THE PARTIES

5. Plaintiff ARIAD is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 40 Landsdowne Street, Cambridge, Massachusetts 02139. ARIAD is the assignee and owner of the '874 patent, as evidenced by the assignment documents recorded in the PTO and the face of the '874 patent.

¹ The parties' proposed remand order and the remand order entered by the Court in case number 1:12-cv-886-TSE-TRJ (E.D. Va.) did not specify whether a challenge to the PTO's patent term adjustment determination on remand should be filed as a new action or asserted in an amended complaint in that action. To avoid any question about the proper procedure, ARIAD is filing both this complaint and an amended complaint in case number 1:12-cv-886-TSE-TRJ (E.D. Va.). ARIAD will seek that the two actions be consolidated.

6. Defendant Joseph Matal is the Acting Under Secretary of Commerce for Intellectual Property and Director of the PTO (“Director”), acting in his official capacity. The Director is the head of the agency, charged by statute with providing management supervision for the PTO and for the issuance of patents. The Director is the official responsible for determining the period of patent term adjustment, *see* 35 U.S.C. § 154(b)(3), and is the proper defendant in a suit seeking review of such determinations, *see id.* § 154(b)(4)(A).

JURISDICTION, VENUE, AND TIMING

7. This Court has subject-matter jurisdiction over this action and is authorized to issue the relief sought pursuant to 28 U.S.C. §§ 1331, 1338(a), 1361, 2201 & 2202; 35 U.S.C. § 154(b)(4)(A); and 5 U.S.C. §§ 701-706.

8. Venue is proper in this district by virtue of 35 U.S.C. § 154(b)(4)(A).

9. This Complaint is timely filed in accordance with this Court’s order in *Ariad Pharmaceuticals, Inc. v. Lee*, No. 1:12-cv-00886-TSE-TRJ, ECF No. 27 (Mar. 31, 2014), and 35 U.S.C. § 154(b)(4)(A). The PTO’s decision on ARIAD’s request for reconsideration was entered on March 9, 2017. ARIAD’s complaint is thus filed within 180 days of the date of the reconsideration decision.

BACKGROUND

The Patent Term Adjustment Statute

10. Under 35 U.S.C. § 154(a)(2), the grant of a patent is for a term ending 20 years from the effective filing date of the patent application. Because this twenty-year period begins to run before a patent is issued, any delay in the PTO’s processing of an application reduces the duration of the patent term.

11. To prevent such delays from decreasing patent term, Congress directed the PTO

to grant successful applicants upward adjustments of their patent terms to compensate for three categories of processing delay by the PTO. These categories of delay, for which compensation is “Guarantee[d],” are set forth in 35 U.S.C. §§ 154(b)(1)(A), (B), and (C), and are commonly known as “A delay,” “B delay,” and “C delay,” respectively. “A delay” accrues when the PTO fails in certain specified ways to respond to the applicant in a timely fashion, such as by failing to provide a notification or notice of allowance within 14 months of the filing of the application or by failing to issue a patent within 4 months of the date on which the issue fee was paid. “B delay” accrues when the PTO fails to issue a patent within three years, excluding certain specified periods of time. “C delay” accrues when there are delays “due to derivation proceedings, secrecy orders, and appeals.”

12. At issue in this case is “B delay.” “B delay” is based on a statutory “Guarantee of no more than 3-year application pendency.” Under this guarantee, applicants are granted additional patent term “if the issue of an original patent is delayed due to the failure of the [PTO] to issue a patent within 3 years after the actual filing date of the application ... in the United States,” but not including (as relevant here) “any time consumed by continued examination of the application requested by the applicant under section 132(b).” 35 U.S.C. § 154(b)(1)(B).

13. Section 132(b) states that the “Director shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant.” *Id.* § 132(b). Under the regulations promulgated by the Director, if prosecution of a patent application is closed by a final action, the applicant may seek continued examination by filing a request for continued examination (“RCE”) and paying a fee. *See* 37 C.F.R. §§ 1.114(a)-(b). “If an applicant timely files a submission and [the fee], the [PTO] *will* withdraw the finality of any Office action and the submission *will* be entered and considered.” *Id.* § 1.114(d) (emphasis

added).

14. The statute thus guarantees issuance of a patent within three years after the filing of the patent application, with certain specified exclusions including time consumed by continued examination. *See* 35 U.S.C. § 154(b)(1)(B)(i). If the PTO fails to meet this guarantee, the statute grants the applicant a remedy by requiring that “the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.” *Id.* § 154(b)(1)(B).

15. On January 15, 2014, the Court of Appeals for the Federal Circuit in *Novartis* held that “B delay” is calculated “by determining the length of time between application and patent issuance, then subtracting any continued examination time ... and determining the extent to which the result exceeds three years.” 740 F.3d at 601. In so holding, the court noted that § 154(b)(1)(B) is “best understood as making distinctions based on whether certain delays are attributable to the PTO.” *Id.* at 602. Under the statute, the court reasoned, applicants are entitled to patent term adjustment (“PTA”) due to delays “plainly attributable to the PTO.” *Id.* The Court rejected the PTO’s position that, where an applicant has filed an RCE, all of the time from that filing until the patent issues is excluded from “B delay,” including the period following a notice of allowance. *Id.* at 602-03. The Court held that the time following a notice of allowance until issuance is not “time consumed by continued examination” that must be excluded from “B delay.” *See id.* at 602 (“The common-sense understanding of ‘time consumed by continued examination,’ 35 U.S.C. § 154(b)(1)(B)(i), is time up to allowance, but not later, unless examination on the merits resumes.”). This is because “[a]n ‘examination’ presumptively ends at allowance, when prosecution is closed and there is no further examination on the merits in the absence of a special reopening.” *Id.* Delay during the “allowance-to-issuance time” is “plainly

attributable to the PTO.” *Id.*

16. Under § 154(b), applicants generally are entitled to a patent term adjustment that compensates them for the sum of all PTO delays. But § 154(b)(2)(A) provides that “[t]o the extent that periods of delay attributable to grounds specified in paragraph [154(b)(1)] overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.” PTO delays “overlap” for purposes of this provision only when they “occur at the same time.” *Wyeth v. Kappos*, 591 F.3d 1364, 1369 (Fed. Cir. 2010) (“*Wyeth*”). In other words, the same day cannot be double-counted as both an “A delay” and a “B delay.” Conversely, if “an A delay occurs on one day and a B delay occurs on a different day, those two days do not ‘overlap’ under section 154(b)(2).” *Id.* at 1370. Further, the fact that an “A delay” in some respect contributed to a “B delay” does not mean that the two delays overlapped within the meaning of the statute. *See id.* (rejecting the PTO’s argument that “it would be double counting if A and B delays were both used to adjust because A delays ‘cause’ B delays”).

17. Section 154(b)(2)(C)(i) directs that “[t]he period of adjustment of the term of a patent under paragraph [154(b)(1)] shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.” Such a period of time is commonly known as “applicant delay.”

18. Under 35 U.S.C. § 154(b)(4)(A), “[a]n applicant dissatisfied with the Director’s decision on the applicant’s request for reconsideration under paragraph (3)(B)(ii) shall have exclusive remedy by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia within 180 days after the date of the Director’s decision on the applicant’s request for reconsideration.”

Proceedings in the PTO with Respect to the '874 Patent

19. The proceedings in the PTO with respect to the '874 patent are reflected in the administrative record and are summarized in relevant respects as follows:

20. U.S. patent application number 11/644,849 was filed on December 22, 2006.

21. On May 12, 2008, the PTO mailed a restriction requirement. On November 17, 2008, the applicant filed a response to the restriction requirement.

22. On December 11, 2008, the PTO mailed a first non-final action. On June 11, 2009, the applicant mailed a response to the first non-final action. On June 15, 2009, the PTO received the applicant's response.

23. On August 3, 2009, the PTO mailed a final action rejecting the patent application.

24. On February 3, 2010, the applicant mailed a response to the final action and a request for continued examination under 35 U.S.C. § 132(b), along with the required fee. On February 12, 2010, the PTO received the applicant's response and request for continued examination, per the PTO's records.

25. On February 16, 2010, the PTO erroneously concluded that the patent application had been abandoned for failure to respond to the August 3, 2009 office action, despite the fact that the applicant had timely filed a response to the final action and a request for continued examination. On February 19, 2010, the PTO mailed a notice of abandonment, citing the applicant's alleged failure to file a response to the final action. On February 25, 2010, the applicant filed a petition to withdraw the holding of abandonment, noting that it had timely filed a response.

26. On March 29, 2010, the applicant filed a supplemental information disclosure statement.

27. On May 13, 2010, the PTO granted the petition to withdraw the holding of abandonment. The decision granting the petition, which is attached hereto as Exhibit 2, notes that abandonment was improper because a “review of Office records reveals that the Office received the reply on February 12, [2010].” Exh. 2 at 1. Notably, in the decision, the PTO stated that “[t]he application *will be* referred to Technology Center Art Unit 1624 ... *for continued examination in the normal course of business*,” thus conceding that “continued examination” had not yet started. *Id.* at 2 (emphasis added).

28. On June 10, 2010, the PTO issued a notice of rescinded abandonment and forwarded the case to the examiner for the continued examination requested by the applicant to commence. *See* Exh. 3 (Patent Application Information Retrieval (“PAIR”) Transaction History). Prior to this time, the PTO had not begun continued examination because of its erroneous conclusion that the patent application had been abandoned.

29. On October 13, 2010, the PTO mailed a second non-final action. On April 18, 2011, the applicant filed a response to the second non-final action.

30. On October 13, 2011, the PTO mailed a notice of allowance.

31. On December 6, 2011, the applicant filed an amendment under 37 C.F.R. § 1.312. On January 3, 2012, the PTO mailed a response to Rule 312 communication and corrected notice of allowability.

32. On February 14, 2012, the PTO issued the ’874 patent, with a calculated PTA under 35 U.S.C. § 154(b) of 0 days.

Proceedings Following the Issuance of the ’874 Patent

33. On April 11, 2012, the patentee filed a petition for reconsideration of patent term adjustment pursuant to 37 C.F.R. § 1.705(d). On May 14, 2012, the PTO dismissed the petition

for reconsideration.

34. On July 14, 2012, the patentee filed a petition to the Director pursuant to 37 C.F.R. § 1.181. On August 22, 2012, the PTO denied the petition to the Director.

35. On August 9, 2012, ARIAD filed a civil action pursuant to 35 U.S.C. § 154(b)(4)(A) in the United States District Court for the Eastern District of Virginia. On March 31, 2014, ARIAD and the PTO filed a Joint Motion To Remand. The Joint Motion explained that a remand to the PTO was “appropriate to allow the agency to recalculate the patent term adjustment to which the ’874 patent is entitled in light of the Federal Circuit’s ruling in *Novartis*.” *Ariad Pharm., Inc. v. Lee*, No. 1:12-cv-00886-TSE-TRJ, ECF No. 26, at 2 (E.D. Va. Mar. 31, 2014).

36. On March 31, 2014, the Court remanded the case to the PTO for recalculation of the PTA in light of *Novartis*. The Court directed that “the PTO shall make a determination under 35 U.S.C. § 154(b)(3)(B) and set forth a time period during which the patentee can request reconsideration.” *Ariad Pharm., Inc. v. Lee*, No. 1:12-cv-00886-TSE-TRJ, ECF No. 27, at 1 (E.D. Va. Mar. 31, 2014). The Court specifically stated that in the event “that the patentee seeks reconsideration within the time period provided by the USPTO in the determination, the USPTO’s decision on the patentee’s request for reconsideration shall be reviewable under 35 U.S.C. § 154(b)(4).” *Id.*

37. On January 28, 2016, ARIAD filed a petition under 37 C.F.R. § 1.182, requesting that the PTO comply with the court order that the PTO recalculate the PTA for the ’874 patent. On April 19, 2016, the PTO issued a decision purporting to recalculate the PTA in light of *Novartis*, but continued to find that the period of patent term adjustment was 0 days. *See* Exh. 4. On June 9, 2016, ARIAD filed a timely request for reconsideration of the PTO’s determination,

which is attached hereto as Exhibit 5. On March 9, 2017, the PTO issued a decision on ARIAD's request for reconsideration, denying the PTA adjustment. That decision is attached hereto as Exhibit 6.

The Challenged PTO Determination of PTA

38. The PTO's April 19, 2016 Decision upon Remand and Reconsideration of Patent Term Adjustment and Notice of Intent To Issue Certificate of Correction and Decision on Petition, and the PTO's March 9, 2017 Decision on Request for Reconsideration of Decision, were contrary to the plain terms of § 154(b)(1)(B), failed adequately to address the relevant considerations, and did not reflect reasoned decisionmaking.

The PTO's Incorrect Calculation of Patent Term Adjustment

39. The patent term adjustment set forth on the face of the issued '874 patent is 0 days. The PTO's decisions following remand and on ARIAD's request for reconsideration similarly set forth a PTA of 0 days.

40. ARIAD and the PTO both agree that the period of "A delay" is 203 days, based on the 80 days that lapsed between February 23, 2008 (the day after the date that is fourteen months from the filing of the application) and May 12, 2008 (the date the restriction was mailed) pursuant to 37 C.F.R. § 1.703(a)(1) and the 123 days that lapsed between June 13, 2010 (the day after the date that is four months from the date a request for continued examination was filed) and October 13, 2010 (the date the non-final action was mailed) pursuant to 37 C.F.R. § 1.703(a)(1). Further, ARIAD and the PTO both agree that the period of "C delay" is 0 days, the period of "overlap" is 0 days, and the period of "applicant delay" is 463 days. ARIAD and the PTO also both agree that the proper formula for calculating PTA is to subtract any "overlap" and "applicant delay" from the sum of all "A delay," "B delay," and "C delay." Finally, ARIAD

and the PTO both agree that the correct formula for calculating “B delay” under *Novartis* is to subtract any continued examination time from the number of days between the application and the issuance of the patent, and then determine the extent to which that result exceeds three years. ARIAD and the PTO disagree only on the length of continued examination time that should be used to calculate “B delay.”

41. Following remand, the PTO calculated “B delay” as 175 days. The PTO arrived at that conclusion based on the following calculation: 1881 days (time between filing date and patent issuance) minus 609 days (“time consumed by continued examination”) minus 1097 days (time between filing date and three years after filing date).

42. ARIAD agrees with the PTO that the time between the filing date and the patent issuance is 1881 days. ARIAD also agrees with the PTO that the time between the filing date and three years after the filing date is 1097 days. ARIAD does not agree, however, that the “time consumed by continued examination” is 609 days. The PTO arrived at 609 days by improperly counting the entire period between the date of the filing of the RCE (February 12, 2010) and the date of mailing of the Notice of Allowance (October 13, 2011) as “time consumed by continued examination” that must be excluded from the period of “B delay” under § 154(b)(1)(B)(i).

43. In fact, as explained below, continued examination was not occurring during the 118-day period between February 12, 2010 and June 10, 2010 because the PTO had failed to recognize that it had received applicant’s RCE and had therefore erroneously concluded that the patent application had been abandoned. Continued examination did not commence until June 10, 2010 when the case was forwarded to the examiner. *See* Exh. 3. The PTO’s conclusion that continued examination was occurring even though the PTO admits it was not actually engaged in

examination during the 118-day period between February 12, 2010 and June 10, 2010 was contrary to § 154(b)(1)(B)(i) and rested on an incorrect interpretation of that provision. There can be no overlap between “abandonment” and “continued examination.” Because the PTO *treated* the patent application as abandoned for 118 days, it cannot now revise history to assert that the patent application was under continued examination during this period. As a result, the period consumed by continued examination was only 491 days, not 609 days, and the PTO’s conclusion that the period of “B delay” was 175 days was contrary to § 154(b)(1)(B)(i).

44. This improper calculation of “B delay” led to an incorrect determination of 0 days of PTA. The PTO arrived at its determination of PTA based on the following calculation: 378 days (the sum of 203 days of “A delay,” 175 days of “B delay,” and 0 days of “C delay”) minus 463 days (the “applicant delay”). Because the calculation led to a negative number, the PTO determined that no PTA was warranted. The PTO’s determination of PTA was therefore contrary to § 154(b)(1)(B)(i).

The Correct Calculation of Patent Term Adjustment for the '874 patent

45. The correct calculation of “B delay” is 293 days, not 175 days. The PTO’s 175-day calculation improperly counts the entire period between the date of filing of the RCE and the date of mailing of the Notice of Allowance as “time consumed by continued examination.” But a significant portion of that time (118 days) occurred before the PTO had even commenced continued examination due to the PTO’s admittedly mistaken abandonment of the application.

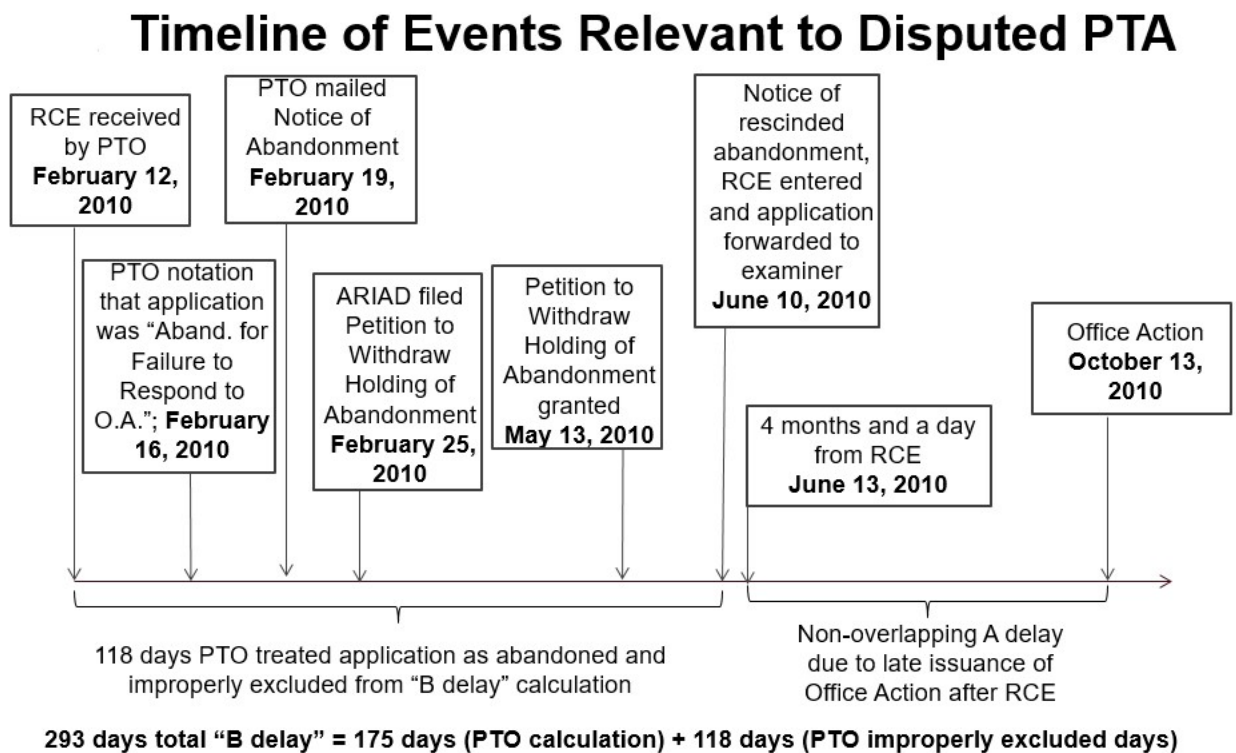
46. The 118 days of the PTO’s erroneous abandonment—from its receipt of the RCE filing (February 12, 2010) to the date that PTO records indicate examination resumed following improper abandonment (June 10, 2010)—should have been excluded from the PTO’s calculated 609 days between filing of the RCE and the Notice of Allowance. No continued examination

occurred during those 118 days, and thus that time was not “consumed by” continued examination.

47. The statutory language of 35 U.S.C. § 154(b)(1)(B) makes clear that delay as a result of the PTO’s improper abandonment, even after RCE filing, constitutes “B delay.” Specifically, Congress’s use of the phrase “consumed by continued examination” in § 154(b)(1)(B)(i) instead of “*after* the request for continued examination” indicates that a period is excluded from “B delay” only if the PTO is actually engaged in continued examination. The Federal Circuit’s decision in *Novartis* confirms that plain reading. *See Novartis*, 740 F.3d at 602 (time after a notice of allowance was not “consumed by continued examination” because examination “presumptively ends at allowance”). A period of 118 days during which a patent application was mistakenly abandoned by the PTO is a delay “plainly attributable to the PTO.” *Id.*; *see also Pfizer, Inc. v. Lee*, 811 F.3d 466, 476 (Fed. Cir. 2016) (“The underlying purpose of PTA is to compensate patent applicants for certain reductions in patent term that are not the fault of the applicant.” (internal quotation marks and alterations omitted)). In this case, the PTO had not even commenced continued examination during the period in question because of its erroneous conclusion that the patent application had been abandoned. This is not a case where the patentee objects to the pace of the PTO’s continued examination or actions taken by the PTO that led to the filing of an RCE. *Compare Maas v. Lee*, 189 F. Supp. 3d 581, 585 (E.D. Va. 2016) (rejecting *pro se* patentee’s argument that continued examination time should be included in PTA under § 154(b)(2) because it was not attributable to applicant delay). Here, the PTO did not even begin continued examination, because of its mistaken conclusion that the application had been abandoned, until June 10, 2010. The period between February 12, 2010 and June 10, 2010 should not have been excluded from “B delay.”

48. Accordingly, the total “B delay” that was not “time consumed by continued examination” should be 293 days. That number is calculated based on the following formula: 1881 days (time between filing date and patent issuance) minus 491 days (“time consumed by continued examination”) minus 1097 days (time between filing date and three years after filing date).

49. There is also no “overlap” problem with ARIAD’s calculation. In its ruling on ARIAD’s request for reconsideration, the PTO argued that “based on a determination that the abandonment was improper and thus, should be withdrawn, appropriate [A] delay was accorded” for the period from June 13, 2010 to October 13, 2010. (Exh. 6 at 5). But because the relevant period of “B delay” was from February 12, 2010 to June 10, 2010 (the period during which the PTO abandoned ARIAD’s application), there is no overlap of “A delay” and “B delay” under the definition put forth by the Federal Circuit in *Wyeth*, as shown in the diagram below:



50. Because the proper “B delay” is 293 days, ARIAD is entitled to 33 days of PTA. That number is calculated based on the following formula: 496 days (the sum of 203 days of “A delay,” 293 days of “B delay,” and 0 days of “C delay”) minus 463 days (the “applicant delay”).

The PTO’s Failure To Address the Relevant Factors and Engage in Reasoned Decisionmaking

51. The PTO on remand failed to address the factors relevant to its calculation of “B delay” or to engage in reasoned decisionmaking.

52. The PTO failed to adequately address the plain language of § 154(b)(1)(B)(i). ARIAD in its request for reconsideration had explained that § 154(b)(1)(B)(i) excludes only time actually “consumed” by continued examination. *See* Exh. 5 at 6-7. The PTO, however, did not address that straightforward contention.

53. The PTO also failed to address the Federal Circuit’s reasoning in *Novartis*. As explained above, the Federal Circuit in *Novartis* made clear that a period will be excluded from “B delay” under § 154(b)(1)(B)(i) only if “examination” was actually occurring during that period. *See Novartis*, 740 F.3d at 602. Although ARIAD pointed this out to the PTO, *see* Exh. 5 at 7, the PTO never acknowledged that its approach was contrary to the Court’s reasoning in *Novartis*.

54. The PTO nowhere disputed that during the time period between February 12, 2010 and June 10, 2010, the agency was not actually engaged in continued examination of the patent application. The PTO’s May 13, 2010 Decision on Petition (Exh. 2) acknowledged that a “review of Office records reveals that the Office received [applicant’s reply to the August 3, 2009 final Office action and RCE] on February 12, [2010].” Exh. 2 at 1. But the Decision makes clear that up until that point the patent application had not been referred to the proper unit “for processing of the reply, and for continued examination.” *Id.* at 2. And the PTO does not

deny that the application was not, in fact, referred for continued prosecution to commence until June 10, 2010. *See* Exh. 3. Yet the PTO never explains how the period between February 12, 2010 and June 10, 2010 could have been “consumed by continued examination of the application” if the PTO had not yet commenced such continued examination due to its own admitted error.

55. Rather than address the undisputed fact that the PTO was not engaged in continued examination between February 12, 2010 and June 10, 2010, the PTO’s Decision on Request for Reconsideration sidesteps the issue. It contends that because the Office in its May 13, 2010 Decision on Petition admitted its error and withdrew its erroneous conclusion that the application had been abandoned, “there is no period of abandonment in this application.” Exh. 6 at 5. The PTO thus reasoned that “even if [ARIAD’s] argument were persuasive that the ‘time consumed by continued examination’ should not include any period of abandonment, such argument is not relevant to the determination of patent term adjustment in this patent.” *Id.* The PTO’s argument, however, fails to address the salient point—that the PTO had not even commenced continued examination during the period in question. The fact that the PTO acknowledged that this failure was due to its own error—not the applicant’s abandonment of the application—provides no basis to conclude that the PTO actually had been examining the application.

56. Finally, the PTO relied on a January 9, 2015 final rule making changes to the PTO’s regulations in light of the Federal Circuit’s decision in *Novartis*. *See* Exh. 6 at 4 (quoting *Changes to Patent Term Adjustment in View of the Federal Circuit Decision in Novartis v. Lee*, 80 Fed. Reg. 1346, 1348 (Jan. 9, 2015)). The final rule, however, did not address the question presented in this case—whether time when the PTO has erroneously failed even to commence

the continued examination requested by the applicant is time “consumed by continued examination.”

CLAIMS FOR RELIEF

**COUNT ONE
(35 U.S.C. § 154)**

57. Plaintiff incorporates paragraphs 1-56 as if fully set forth herein.

58. The PTO’s calculation of the “B delay” for the ’874 patent was based on an interpretation of 35 U.S.C. § 154(b)(1)(B) that improperly construed the phrase “time consumed by continued examination” to include time before “continued examination” had even commenced.

59. The PTO’s incorrect calculation of the “B delay” for the ’874 patent led to an incorrect calculation of the total patent term adjustment for the ’874 patent. The PTO’s calculation of the total patent term adjustment for the ’874 patent was thus based on an improper interpretation of 35 U.S.C. § 154(b)(1)(B).

60. The PTO’s decisions determining PTA failed to address the relevant factors, including the plain text of § 154(b)(1)(B)(i), the reasoning of the Federal Circuit in *Novartis*, and the PTO’s own admission that it had not, in fact, even commenced continued examination during the period at issue. The PTO also failed to engage in reasoned decisionmaking, relying instead on irrelevant contentions.

61. The PTO’s patent term adjustment calculation of 0 days for the ’874 patent was contrary to its statutory jurisdiction and authority, arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law under 5 U.S.C. § 706(2).

62. ARIAD is entitled to an additional 33 days of patent term for the ’874 patent.

63. ARIAD has adequately exhausted all of its available administrative remedies

under 35 U.S.C. § 154 or, in the alternative, pursuit of any further administrative remedies is futile or otherwise not required.

COUNT TWO
(Administrative Procedure Act, 5 U.S.C. § 702 et seq.)

64. Plaintiff incorporates paragraphs 1-63 as if fully set forth herein.

65. The PTO's calculation of the "B delay" for the '874 patent was based on an interpretation of 35 U.S.C. § 154(b)(1)(B) that improperly construed the phrase "time consumed by continued examination" to include time before "continued examination" had even commenced.

66. The PTO's incorrect calculation of the "B delay" for the '874 patent led to an incorrect calculation of the total patent term adjustment for the '874 patent. The PTO's calculation of the total patent term adjustment for the '874 patent was thus based on an improper interpretation of 35 U.S.C. § 154(b)(1)(B).

67. The PTO's decisions determining PTA failed to address the relevant factors, including the plain text of § 154(b)(1)(B)(i), the reasoning of the Federal Circuit in *Novartis*, and the PTO's own admission that it had not, in fact, even commenced continued examination during the period at issue. The PTO also failed to engage in reasoned decisionmaking, relying instead on irrelevant contentions.

68. The PTO's patent term adjustment calculation of 0 days for the '874 patent was contrary to its statutory jurisdiction and authority, arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law under 5 U.S.C. § 706(2).

69. ARIAD is entitled to an additional 33 days of patent term for the '874 patent.

70. The PTO's determination of PTA for the '874 patent was a final agency action that is reviewable by a district court in accordance with 5 U.S.C. § 704.

71. ARIAD has adequately exhausted all of its available administrative remedies under 35 U.S.C. § 154 or, in the alternative, pursuit of any further administrative remedies is futile or otherwise not required.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that this Court:

1. Hold unlawful and set aside Defendant's determination of patent term adjustment for the '874 patent;
2. Declare that Defendant's determination of PTA for the '874 patent was unlawful and that the correct patent term adjustment for the '874 patent is 33 days;
3. Order Defendant to correct the patent term adjustment for the '874 patent to 33 days, alter the term of the '874 patent to reflect the corrected adjustment, and issue a certificate of correction reflecting the corrected adjustment and term.
4. Grant such further and other relief as this Court deems just and proper.

Dated: June 26, 2017

Respectfully submitted,

/s/ Kevin Gallagher
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